On Demand PrEP with Oral TDF/FTC in MSM
Results of the ANRS Ipergay Trial


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Disclosures

- Advisory Boards: BMS, Gilead, GSK
  Janssen, Merck, ViiV

- Research Grants: Merck and Gilead
Background

- High number of new HIV infections among MSM in France and Canada
- Conflicting results from PrEP trials with oral daily TDF/FTC: Adherence « Achilles’ heel » of PrEP
- More convenient dosing regimen: « On demand »
- Could improve adherence, safety and cost-effectiveness and make PrEP more attractive
- Supported by animal models
Effect of a Double Dose of oral TDF/FTC (-2h, + 24h)

% Uninfected Macaques

Double dose oral TDF/FTC (n = 6) HR : 16.7 p = 0.006

Untreated Controls (n = 32)

Number of weekly rectal SHIV exposures

Garcia-Lerma et al. Science Trans Med 2010, 14,14ra4
Study Design

**Double-Blinded Randomized Placebo-Controlled Trial**

- HIV negative high risk MSM
- Condomless anal sex with > 2 partners within 6 m
- eGFR > 60 mL/mn

* Full prevention services* TDF/FTC before and after sex

* Full prevention services* Placebo before and after sex

* Counseling, condoms and gels, testing and treatment for STIs, vaccination for HBV and HAV, PEP

- End-point driven study: with 64 HIV-1 infections, 80% power to detect a 50% relative decrease in HIV-1 incidence with TDF/FTC (expected incidence: 3/100 PY with placebo)

- Follow-up visits: month 1, 2 and every two months thereafter
Ipergay : Event-Driven iPrEP

- 2 tablets (TDF/FTC or placebo)
  2-24 hours before sex
- 1 tablet (TDF/FTC or placebo)
  24 hours later
- 1 tablet (TDF/FTC or placebo)
  48 hours after first intake
Study Endpoints

Primary Efficacy Endpoint: HIV-1 infection

- HIV seroconversion using a 4th generation assay combining Ab/Ag detection on serum or detection of HIV-1 RNA in plasma (stored plasma samples used to date time of infection)

Secondary end-points

- Safety and tolerability
- Adherence (pill count, plasma drug levels, computer assisted self-interviews (CASIs)
- Sexual behavior (condom use, number of sexual acts, number of partners)
- Sexually transmitted infections

October 23, 2014 (7th meeting) the DSMB recommended the discontinuation of the placebo arm and that on demand PrEP be offered to all participants
Study Flow-Chart

Screened n=445

Randomized n=414

TDF/FTC n=206

- Did not receive Rx n=7
  - Withdrew consent n=4
  - Lost to follow-up n=2
  - HIV-1 infection n=1

- Included in mITT analysis n=199
  - D/C participation n=23
    - Withdrew consent n=11
    - Lost to follow-up n=7
    - Other n=5

- Followed n=176 (88%)

Placebo n=208

- Did not receive Rx n=7
  - Withdrew consent n=2
  - Lost to follow-up n=3
  - HIV-1 infection n=2

- Included in mITT analysis n=201
  - D/C participation n=24
    - Withdrew consent n=15
    - Lost to follow-up n=6
    - Other n=3

- Followed n=177 (88%)

Excluded n=31 (7%)

- Not meeting eligibility criteria n=11
- Withdrew consent n=8
- Lost to follow-up n=1
- HIV-1 infection n=11
<table>
<thead>
<tr>
<th>Characteristics (Median, IQR) or (n, %)</th>
<th>TDF/FTC n = 199</th>
<th>Placebo n = 201</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>35 (29-43)</td>
<td>34 (29-42)</td>
</tr>
<tr>
<td>White</td>
<td>190 (95)</td>
<td>184 (92)</td>
</tr>
<tr>
<td>Completed secondary education</td>
<td>178 (91)</td>
<td>177 (89)</td>
</tr>
<tr>
<td>Employed</td>
<td>167 (85)</td>
<td>167 (84)</td>
</tr>
<tr>
<td>Single</td>
<td>144 (77)</td>
<td>149 (81)</td>
</tr>
<tr>
<td>History of PEP use</td>
<td>56 (28)</td>
<td>73 (37)</td>
</tr>
<tr>
<td>Use of psychoactive drugs*</td>
<td>85 (44)</td>
<td>92 (48)</td>
</tr>
<tr>
<td>Circumcised</td>
<td>38 (19)</td>
<td>41 (20)</td>
</tr>
<tr>
<td>Infection with NG, CT or TP**</td>
<td>43 (22)</td>
<td>59 (29)</td>
</tr>
<tr>
<td>Nb sexual acts in prior 4 weeks</td>
<td>10 (6-18)</td>
<td>10 (5-15)</td>
</tr>
<tr>
<td>Nb sexual partners in prior 2 months</td>
<td>8 (5-17)</td>
<td>8 (5-16)</td>
</tr>
</tbody>
</table>

* in last 12 months: ecstasy, crack, cocaine, crystal, speed, GHB/GBL
** NG: Neisseria gonorrhoeae, CT: Chlamydia trachomatis, TP: Treponema pallidum
Sexual Behavior

Median Nb of Sexual Acts (last 4 weeks)

- TDF/FTC
- Placebo

Anal Intercourse W/O Condom

- TDF/FTC
- Placebo

Receptive Anal Intercourse W/O Condom

- TDF/FTC
- Placebo

Median Nb of Sexual Partners (2 months)
Sexually Transmitted Infections

- 276 STIs were diagnosed in 141 participants

<table>
<thead>
<tr>
<th>STI</th>
<th>TDF/FTC n=199</th>
<th>Placebo n=201</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nb Pt (%)</td>
<td>Nb Events</td>
<td>Nb Pt (%)</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>43 (22)</td>
<td>61</td>
<td>34 (17)</td>
</tr>
<tr>
<td>Gonorrhoeae</td>
<td>38 (19)</td>
<td>50</td>
<td>45 (22)</td>
</tr>
<tr>
<td>Syphilis</td>
<td>19 (10)</td>
<td>19</td>
<td>19 (10)</td>
</tr>
<tr>
<td>HCV</td>
<td>3 (&lt;2)</td>
<td>3</td>
<td>3 (&lt;2)</td>
</tr>
<tr>
<td>Any STI</td>
<td>76 (38)</td>
<td>133</td>
<td>65 (32)</td>
</tr>
</tbody>
</table>
KM Estimates of Time to HIV-1 Infection (mITT Population)

Mean follow-up of 13 months: 16 subjects infected
14 in placebo arm (incidence: 6.6 per 100 PY), 2 in TDF/FTC arm (incidence: 0.94 per 100 PY)

86% relative reduction in the incidence of HIV-1 (95% CI: 40-99, p=0.002)
NNT for one year to prevent one infection: 18
Adherence by Pill Count

- **Median number of pills/month (IQR):** 16 pills (10-23) in the placebo arm and 16 pills (12-24) in the TDF/FTC arm (p=0.84)

- **48 participants (12%)** received PEP. 25 (13%) in the TDF/FTC arm and 23 (11%) in the placebo arm (p=0.73)
Adherence Assessed by CASIs

PrEP use during the last sexual intercourse

1212 sexual intercourses assessed in 319 participants

<table>
<thead>
<tr>
<th>% PrEP Use (min-max)</th>
<th>TDF/FTC n = 649 acts</th>
<th>Placebo n = 563 acts</th>
<th>Total % (min-max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct use*</td>
<td>45 (36-57)</td>
<td>40 (22-49)</td>
<td>43 (35-51)</td>
</tr>
<tr>
<td>Suboptimal use</td>
<td>27 (14-35)</td>
<td>31 (18-44)</td>
<td>29 (20-38)</td>
</tr>
<tr>
<td>No PrEP</td>
<td>27 (15-37)</td>
<td>29 (24-44)</td>
<td>28 (20-38)</td>
</tr>
</tbody>
</table>

* According to the protocol, or at least one pill before and one pill after sex
# Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>TDF/FTC n=199</th>
<th>Placebo n=201</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any AE</td>
<td>184 (92)</td>
<td>178 (89)</td>
<td>0.18</td>
</tr>
<tr>
<td>Any Serious AE</td>
<td>18 (9)</td>
<td>16 (8)</td>
<td>0.70</td>
</tr>
<tr>
<td>Any Grade 3 or 4 AE</td>
<td>17 (9)</td>
<td>14 (7)</td>
<td>0.56</td>
</tr>
<tr>
<td>Treatment D/C due to AE</td>
<td>1*</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Drug-Related GI AEs</td>
<td>25 (13)</td>
<td>11 (6)</td>
<td>0.013</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>15</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>11</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

* deep veinous thrombosis with suspected DDI with dabigatran
## Lab Abnormalities

<table>
<thead>
<tr>
<th>Nb of Participants (%)</th>
<th>TDF/FTC n=199</th>
<th>Placebo n=201</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1 Creatinine</td>
<td>28 (14%)*</td>
<td>15 (7%)</td>
<td>0.042</td>
</tr>
<tr>
<td>Proteinuria ≥ 2+</td>
<td>10 (5%)</td>
<td>9 (5%)</td>
<td>0.83</td>
</tr>
<tr>
<td>Glycosuria ≥ 2+</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>All Grades ALAT</td>
<td>33 (17%)</td>
<td>26 (13%)</td>
<td>0.37</td>
</tr>
<tr>
<td>Grade 3 or 4 ALAT</td>
<td>1 (1%)**</td>
<td>4 (4%)***</td>
<td>0.36</td>
</tr>
</tbody>
</table>

* 2 Participants in the TDF/FTC arm had a transient creatinine clairance < 60 ml/mn
** Acute HCV infection
*** Acute HCV infection in 3 and syphilis in one
Conclusions

- In this population of high risk MSM, incidence of HIV-1 infection in the placebo arm was higher than expected.
- “On Demand” oral PrEP with TDF/FTC was very effective with a 86% (95% CI: 40-99) reduction in HIV-incidence.
- Adherence to PrEP was good supporting the acceptability of “on demand” PrEP.
- Safety of “on demand” TDF/FTC was overall similar to placebo except for gastrointestinal AEs.
- No evidence of risk compensation.
Acknowledgments

- The Participants
- The Study Staff and Peer-Counselors
- The Trial Scientific Committee
- The DSMB
- The Community Advisory Board
- The ANRS Staff
- INSERM SC10-US19
Acknowledgments

- **The Study Staff and Peer-Counselors**
  - Montréal: C. Beauvais, P. Arlotto, C. Fortin, A. Talbot, A. McKenzie, M. Blanchette, R; Rousseau, K. Montheuth, D. Thompson, M. Morin, M. Wainberg, C. Tremblay
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  - Nantes: C. Bernaud, M. Besnier, B. Bonnet, N. Hall, M. Cavellec, H. Hue, L. Larmet, M. Colas, R. Choquet, F. Raffi


- **The DSMB**: AM Taburet, VK Nguyen, Y. Yazdanpanah, C. Taeron, D. Costagliola

- **The Community Advisory Board**: S. Karoun, D. Villard (Action Santé Alternative), JM Astor (Boucle Rouge), D. Ganaye (Federation LGBT), T. Craig (Act-Up), B. Brive (J’y suis j’y reste), R. Orioli (les flamands roses), M. Vanheded (Solidarite SIDA), H. Baudoin (Sida info service), H. Fisher (TRT-5)


- **INSERM UMR 912**: B. Spire, M. Suzan, G. Cattin, B. Demoulin, L. Sagan-Teysissier, N. Lorente

- **ANRS**: V. Doré, I. Porteret, L. Marchand, S. Lemanestre, A. Menecier, N. Etien, MC Simon, JF Delfraissy


- **Rezo Canada**: D. Thompson

- **Canadian Trial Network**: J. Sas, J. Pankovitch, M. Klein, A. Anis

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- **Fondation Pierre Bergé/SIDACTION**: anRS

- **Gilead**: J. Rooney, A. Cheng, P. Petour, C. Rabian
Pragmatic Open-Label Randomised Trial of Pre-Exposure Prophylaxis: the PROUD study

http://www.proud.mrc.ac.uk/
Disclaimers

- Gilead Sciences plc provided drug free of charge, and distributed it to participating clinics
- Gilead Sciences plc provided funds for the additional diagnostics including the pharmacokinetic sub-study
Sexual health service in England

- ~220 sexual health clinics, linked through professional guidelines
- Accessed by 110,000 HIV negative gay men per year
- Diagnoses made and services provided reported to Public Health England
Rationale

• To determine whether PrEP worked as well as iPrEx in this setting (44% reduction in HIV)

• Why might effectiveness be less in real world?
  • Adherence less
    • trial schedules monthly
    • well resourced for adherence support

• Behaviour riskier
  • participants constantly reminded that they could be on placebo, and that effectiveness was unknown
  • well resourced for behaviour change interventions
PROUD Pilot

GMSM reporting UAI last/next 90days; 18+; and willing to take a pill every day

Randomize HIV negative MSM (exclude if treatment for HBV/Truvada contra-indicated)

Risk reduction includes Truvada **NOW**

Risk reduction includes Truvada **AFTER 12M**

Follow **3 monthly** for up to 24 months

Main endpoints in Pilot: recruitment and retention
From April 2014: HIV infection in first 12 months
Designed to mimic real-world

- Eligibility: routine clinic data and p24Ag/Ab serology at enrolment (no PCR)
- Safety: serum creatinine when starting and annually; additional tests if 1+ protein on dipstick
- STIs: (mainly) quarterly HIV, syphilis, HCV, gonorrhoea and chlamydia according to routine clinic
- Behaviour change interventions according to routine clinic (sexual risk, adherence, addiction)

- Study procedures: web-randomisation, data entry, participant-completed questionnaires
Results:
Population, Prescribing, Tolerability
Participant randomization

545 enrolled

- 276 assigned to IMMEDIATE
- 269 assigned to DEFERRED
Baseline demographics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Immediate</th>
<th>Deferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (IQR)</td>
<td>35 (30 – 43)</td>
<td>35 (29 – 42)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>White</td>
<td>80%</td>
</tr>
<tr>
<td>Born UK</td>
<td>No</td>
<td>40%</td>
</tr>
<tr>
<td>Education</td>
<td>University</td>
<td>59%</td>
</tr>
<tr>
<td>Employment</td>
<td>Full-time</td>
<td>70%</td>
</tr>
<tr>
<td>Sexuality</td>
<td>Gay</td>
<td>96%</td>
</tr>
<tr>
<td>Current relationship</td>
<td>No</td>
<td>53%</td>
</tr>
<tr>
<td>Recreational drug use</td>
<td>Yes</td>
<td>76%</td>
</tr>
</tbody>
</table>

1 539/545 (99%) questionnaires returned
2 in the last 90 days
## Prescriptions of PrEP and PEP

<table>
<thead>
<tr>
<th>Immediate</th>
<th>Deferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 14 (5%) never started PrEP</td>
<td>• Anecdotally, rare use of PrEP</td>
</tr>
<tr>
<td>• 156 (56%) prescribed sufficient drug for 100% daily dosing</td>
<td></td>
</tr>
<tr>
<td>• Overall, drug prescribed covered 86% of days in follow-up</td>
<td></td>
</tr>
</tbody>
</table>

- 13 (5%) prescribed PEP (total 15 prescriptions)
- 83 (31%) prescribed PEP (total 174 prescriptions)
PrEP interruptions for medical event

• **PrEP interrupted** by 28 participants *(both groups)* but only 13 had events considered related to drug:
  – nausea alone or with diarrhoea/abdominal pain/aches and fatigue (n=5)
  – decline in creatinine clearance (n=2)
  – headache (n=2)
  – joint pain, with fatigue in one case (n=2)
  – sleep disturbance (n=1)
  – flu-like illness (n=1)

• **PrEP re-started** by 11 of 13 participants above
Results:
HIV endpoint
545 enrolled

276 assigned to IMMEDIATE
- 2 HIV +ve at enrolment
- 7 no HIV test after enrolled
  - 267 contribute to effectiveness analysis

269 assigned to DEFERRED
- 1 HIV +ve at enrolment
- 12 no HIV test after enrolled
  - 256 contribute to effectiveness analysis

**Calculation of person-years:**
From enrolment to the first of the following
- HIV test at m12, or
- HIV test at the time of access to PrEP, or
- diagnosis of HIV infection
Completeness of follow-up for HIV

• **Expected** person-years calculated assuming they had precisely followed protocol schedule

**Observed/expected follow-up:**

• Immediate: 239/261 person years (92%)
• Deferred: 214/242 person years (88%)
Individual incident HIV infections

<table>
<thead>
<tr>
<th>Immediate PrEP</th>
<th>N=3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deferred PrEP</th>
<th>N=19</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## HIV Incidence

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of infections</th>
<th>Follow-up (PY)</th>
<th>Incidence (per 100 PY)</th>
<th>90% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>22</td>
<td>453</td>
<td>4.9</td>
<td>3.4–6.8</td>
</tr>
<tr>
<td>Immediate</td>
<td>3</td>
<td>239</td>
<td>1.3</td>
<td>0.4–3.0</td>
</tr>
<tr>
<td>Deferred</td>
<td>19</td>
<td>214</td>
<td>8.9</td>
<td>6.0–12.7</td>
</tr>
</tbody>
</table>

**Efficacy** = 86% (90% CI: 58 – 96%)

**P value** = 0.0002

**Rate Difference** = 7.6 (90% CI: 4.1 – 11.2)

**Number Needed to Treat** = 13 (90% CI: 9 – 25)
Drug Resistance

• 3 of 6 individuals who were seroconverting around baseline (immediate group) or month 12 (deferred group) developed $\text{M184V/I}$ mutations (as a mixture with wild type)

• $\text{K65R}$ was not detected
Results:

STI endpoints
STIs

<table>
<thead>
<tr>
<th>Condition</th>
<th>Immediate</th>
<th>Deferred</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any STI</td>
<td>p=0.08</td>
<td>p=0.44</td>
</tr>
<tr>
<td>Gonorrhoea</td>
<td>p=0.44</td>
<td>p=0.08</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>p=0.32</td>
<td>p=0.44</td>
</tr>
<tr>
<td>Syphilis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectal GC/CT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Number of screens differed between the groups: e.g. Rectal gonorrhoea/chlamydia 974 in the IMM group and 749 in the DEF
Results:

Sexual behaviour
# Reported sexual behaviour (preliminary)

## Anal sex partners in last 90 days

### BASELINE n=539

<table>
<thead>
<tr>
<th></th>
<th>Immediate Median (IQR)</th>
<th>Deferred Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of partners</td>
<td>10.5 (5-20)</td>
<td>10 (4-20)</td>
</tr>
<tr>
<td>Condomless partners, participant receptive</td>
<td>3 (1-5)</td>
<td>2 (1-5)</td>
</tr>
<tr>
<td>Condomless partners, participant insertive</td>
<td>2.5 (1-6)</td>
<td>3 (1-7)</td>
</tr>
</tbody>
</table>

### MONTH 12 n=349

<table>
<thead>
<tr>
<th></th>
<th>Immediate Median (IQR)</th>
<th>Deferred Median (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of partners</td>
<td>10 (3-24)</td>
<td>8 (3-15)</td>
</tr>
<tr>
<td>Condomless partners, participant receptive</td>
<td>3 (1-8)</td>
<td>2 (1-5)</td>
</tr>
<tr>
<td>Condomless partners, participant insertive</td>
<td>3 (1-8)</td>
<td>3 (1-6)</td>
</tr>
</tbody>
</table>
Conclusions

• HIV incidence in the population who came forward to access PrEP was much higher than predicted based on all MSM attending sexual health clinics
• Despite extensive use of PEP in the deferred period
• Our concerns about PrEP being less effective in the real world were unfounded

• MSM incorporated PrEP into existing risk reduction strategies which continued to include condom use
• There was no difference in STIs, which were common in both groups

• Clinics were able to adapt routine practice to incorporate PrEP
Acknowledgements (1)

Study participants

MRC CTU at UCL
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**Trial Steering Committee**

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**University of Liverpool:** Saye Khoo

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**Clinics:** Anthony Bains, Alan McOwan (Lead),

**MRC CTU at UCL:** Sheena McCormack, Mitzy Gafos, Annabelle South

**Social Science Advisory Group**

**Interviewers:** Caroline Rae, Gill Bell, Michael Rayment, Sonali Wayal, Will Nutland, Mitzy Gafos

**Advisors:** Ingrid Young, Ford Hickson, Lisa McDaid, Marsha Rosengarten, Nicolas Lorente, Agata Pacho, Elizabeth Poliquin, Anthony Nardone, Catherine Dodds, Adam Bourne, David Dolling, Sheena McCormack, Rob Horne